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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/615,643	07/13/2000	Thomas L. Meredith	N-6089RSM	4680

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WADDEY & PATTERSON  
414 UNION STREET, SUITE 2020  
BANK OF AMERICA PLAZA  
NASHVILLE, TN 37219

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/615,643

Applicant(s)

MEREDITH, THOMAS L.

Examiner

Brian E Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 and 21-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 21-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☒ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 6) ☐ Other:

## DETAILED ACTION

### *Response to Amendment*

The declaration filed on 3/4/02 under 37 CFR 1.131 has been considered but is ineffective to overcome the Boyce reference.

The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Boyce reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). A general allegation that the invention was completed prior to the date of the reference is not sufficient. *Ex parte Saunders*, 1883 C.D. 23, 23 O.G. 1224 (Comm'r Pat. 1883). Similarly, a declaration by the inventor to the effect that his or her invention was conceived or reduced to practice prior to the reference date, without a statement of facts demonstrating the correctness of this conclusion, is insufficient to satisfy 37 CFR 1.131. The declaration and exhibits must clearly explain *which facts* or data applicant is relying on to show *completion* of his or her invention prior to the particular date. Vague and general statements in broad terms about what the exhibits describe along with a general assertion that the exhibits describe a reduction to practice "amounts essentially to mere pleading, unsupported by proof or a showing of facts" and, thus, does not satisfy the requirements of 37 CFR 1.131(b).. For example, applicant claims in Attachment B the invention was fully disclosed, but fails to show **all** the features that are

Art Unit: 3738

being claimed. There is no evidence of cortical bone used in Attachment B or what percent was used. Additionally, how the bone was prepared is not disclosed and it should also be noted that the letter dated 9/11/96 with *ideas* were all proposed thoughts and discuss sintering bone. Sintering is not the same as *grinding*.

**Claim Rejections - 35 USC § 102**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 8, 10-12, 14, 19, 25, 28, 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Glimcher et al. (5565502). Fig. 1 discloses a method of using bone tissue and grinding or milling the bone tissue to form a composite, see also col. 6, lines 53-54. Please note that claims are to be given their broadest reasonable interpretation. In re Pearson, 181 USPQ 641 (CCPA 1974). The use of "substantially cortical bone tissue" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively <sup>unlimiting</sup> ~~unlimited~~. Therefore it can be interpreted that Glimcher discloses cortical bone. Glimcher et al. also disclose to the ground bone particles are within the claimed range of 125-850 microns in size, col. 6, line 55. Glimcher also discloses a binder, such as a cyanoacrylate can be added either before molding or after molding and can be applied by spraying, col. 11, lines 57-64. Glimcher discloses the bone composite can be used for various purposes, bone defects, fractures, etc. (col. 11, lines 50-53, col. 12, lines 35-39) which inherently implies the bone composite is molded and formed into the shape of the area to which it is applied.

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5/20/02

Art Unit: 3738

Claims 1-14, 17, 19, 21-28, 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Boyce et al. (6294187). Boyce et al. disclose a method of grinding cortical bone to produce particles for shaping, col. 4, lines 40-45. Boyce also discloses the bone tissue is substantially demineralized, col. 5, lines 37-39 and col. 6, lines 15-28. Boyce additionally discloses the cortical bone tissue can be greater than 50% and up to 95%, col. 7, lines 48-54. Boyce discloses a method of producing sieved bone particles of specific sizes that fall within the claimed range of 125-850 microns, col. 4, lines 53-58. Binders are soaked or bathed in combination with the bone tissue either before or after molding the bone tissue and include cyanoacrylates or fibrin, col. 7, lines 55-62 and col. 8, lines 13-16. The article formed from the bone tissue can be a bone pin or screw, col. 14, lines 6-8. The shaped composite is formed within the claimed range of 14.7 to 30,000 psi, col. 2, lines 40-45.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 15, 16, 18, 29, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce '187. Boyce is explained supra. However, Boyce does not disclose the various cyanoacrylates used and to use a die for shaping the composite. It would have been obvious to one of ordinary skill in the art to use a die for shaping the composite, as dies are well known in the art for shaping bone tissue compositions.

It would have been an obvious matter of design choice to use ester chain or long chain cyanoacrylates, since applicant has not disclosed that using ester chain or long chain cyanoacrylates solves any stated problem or is for any particular purpose and it appears that the cyanoacrylates used would perform equally well with the bone tissue.

### ***Response to Arguments***

Applicant's arguments filed 3/4/02 have been fully considered but they are not persuasive. With respect to Glimcher reference, the functional recitation that the bone tissue is molded to a desired shape has not been given much patentable weight because it is narrative in form with no defined structure or limits. Glimcher's bone composite is fully capable of and is inherently going to be molded to the defect area in which it is applied. Additionally, applicant contends that Glimcher is used for other purposes, different from applicant's intended use. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Regarding the Boyce reference, applicant has not fully established reduction to practice prior to the effective filing date.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 7:30am to 5pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino  
May 16, 2002

TC 3700, AU 3738

  
Paul Prebilic  
Primary Examiner